



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

52991-8

OCT 29 1998

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Findings in FIFRA Good Laboratory Practice (GLP), Books, Records Inspection, and Data Audits At Bedoukian's Technical Pheromones : (Z)-11-Tetradecenyl Acetate (PC No. 128980), (E)-11-Tetradecenyl Acetate (PC No. 129019), (E)-5-Decenol (PC No. 078038), (E)-5-Decenyl Acetate (PC No. 117703), (Z)-Tridecenyl Acetate (PC No. 121901), and (E)-Tridecenyl Acetate: Inspection ID: 9740529911; MRID Nos. 427209-01, 435815-01, 439536-01, and 439537-01, DP Barcode No. D248430 and D249995

FROM: Freshteh Toghrol, Ph.D., Senior Scientist, *F. Toghrol*
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

THRU: Roy Sjoblad, Ph.D. Chief *Roy Sjoblad*
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

TO: Judy Loranger Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

Biochemical Pesticides Branch (BPB) has been asked to review a report of FIFRA GLP compliance inspection, books, and record compliance inspections and data audits conducted on September 23-26, 1997 at Bedoukian Research Inc., 21 Finance Drive Danbury, CT 06810-4192.

BPB is to comment on whether the findings in this report affect the validity of data submitted previously for Bedoukian's Technical Pheromones : (Z)-11-Tetradecenyl acetate, (E)-11-Tetradecenyl acetate MRID Nos. 439536-01 and 439537-01, (E)-5-Decenol, (E)-5-Decenyl acetate (MRID No. 435815-01), (Z)-Tridecenyl acetate, and (E)-Tridecenyl acetate (MRID No. 427209-01).

Audited studies , MRID Nos., the title of the studies, and the results are summarized in the table below:

MRID No.	Lab ID No	Title of study	r e s u l t s
427209-01C	No ID No.	Application for amendment to Bedoukian TPW Technical Pheromone a Biochemical Mating Disruptant for Control of Tomato Pinworm (<i>Keiferia lycopersicella</i>)	Missing raw data for storage stability
439536-01C	No ID No.	Application to Register Bedoukian cis-11-Tetradecenyl acetate Technical Pheromone	No data to support Stability and Storage Stability conclusions
439537-01C	No ID No.	Application to Register Bedoukian trans-11-Tetradecenyl Acetate Technical Pheromone	No data to support Stability and Storage Stability conclusions
435815-01C	No ID No.	Application to Register Bedoukian PTB Technical Pheromone: A Biochemical Mating Disruptant for Control of Peach Twig Borer Manufacturing Use Product	No deficiency

The Conclusion of Lab Audit of 9/23/97 by D. Myer

Findings for the compliance review and the study audit were summarized as follow:

1. For the general books, and records compliance review, no observed negative finding were reported.
2. The inspector noted that the four studies (above MRIDs) Were not conducted under FIFRA GLP (40 CFR 160.135(b)). Additionally, missing raw data 40 CFR 169.2(k) were noted for TPW technical

(MRID No. 427209-01) and cis-11 Tetradecenyl acetate technical (MRID Nos. 439536-01 and 439537-01). This report indicates that the facility had no data archives. The data retention procedures were not clearly defined at the time of inspection.

3. No missing data for Peach Twig Borer (MRID 435815-01).

4. No data to support stability and storage stability conclusions.

Bedoukian's Response and Reason are as follows:

1. Regarding GLP: The reason not following GLP is that 99% of the Bedoukian's business is research and development of flavor and fragrance chemicals, which do not require GLP and only 1% of their sales being due to manufacturing of Pheromones, which are Biopesticides and need GLP.

Additionally, Bedoukian indicated that they are following good science, in their manufacturing process, and producing highly purified technicals, but they do not have the man power to do the paper work for the GLP. Furthermore, their biochemical products are not as toxic as conventional products, they are not directly applied to the crops, and are not affecting non-target organisms. Because of the non-toxic nature of the Pheromones and the fact that the technicals are highly purified, Bedoukian had several meetings with the OPP managements and scientists and was able to convince them to waive the GLP for manufacturing of these Pheromones.

2. Regarding missing data: The reason of missing data was due to a move and since the inspection, Bedoukian official, Robert E. Maloney stated, "I have placed all the data, notes, records, etc. we have for all of our registered Pheromones in a fire proof cabinet in the quality control lab." The lab audit concludes that no additional negative observations were noted during the compliance review.

3. Regarding no data to support stability and storage stability conclusions. Bedoukian indicates that the storage stability of the product is based on years of extensive knowledge of these type of products. Pheromones are esters containing twelve or more carbon atoms, when are stored in normal condition, no significant degradation takes place in 12 to 14 months.

BPB Conclusions:

According to these study audit, all books and records audits indicate that raw data kept by lab matches and supports the submitted data to the Agency. BPB concludes that none of the violations cited in the 6/9/98 report of the Office of Compliance Monitoring are expected to change any conclusions reached by BPPD regarding registration of these products.

cc: F. Toghrol, Judy Loranger, BPPD Subject File,
Jackets: (z) 11-Tetradecenyl Acetate, (E)-11-Tetradecenyl
Acetate, (E)-5-Decenol, (E)-5-Decenyl Acetate, (Z)-Tridecenyl
Acetate, and (E)-Tridecenyl Acetate

F. Toghrol: CM2-902: Tel: 703-308-7014